

*From the office of*  
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May 18, 1999

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The Honorable Tom Harkin  
United States Senate  
731 Hart Senate Office Bldg.  
Washington, DC 20515-2202

Dear Senator Harkin;

I would like for you to consider some action on the enclosed yellow enclosure.

Since you, and our former Congressman Berkley Bedell, had a sincere interest in alternative medicine, and if I remember correctly, you even formed an organization to promote the use of some of the generic and over the counter medications and various treatments for some illnesses, that were found to be effective.

As you are aware, our Sunrise Senior Housing and Estherville Housing accommodates 200 seniors in Estherville, Emmetsburg, Spirit Lake and Spencer. Many of these people order such medication as is indicated in the yellow enclosure. Women's International Pharmacy operates pharmacies in Wisconsin and Arizona and possibly other states. In my own case, I use their liquid DHEA which is compounded by my MD physician.

Please assist us in alleviating this ridiculous act by FDA.

Respectfully,



John L. Jensen

JLJ/ajn

Encl.

cc:FDA

98N-1265

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# CALL TO ACTION

## WE NEED YOUR IMMEDIATE HELP!

*Proposed legislation restricts your rights as a consumer  
and/or as a prescriber of compounded drug products*

**THE FACTS:** Recently, the Food and Drug Administration (FDA) drafted a memorandum of understanding (MOU) intended to provide legislative guidance to State Agencies. As a part of the FDA Modernization Act of 1997, the Food and Drug Administration drafted Section 503A which governs the practice of pharmacy compounding. The MOU, as written, severely limits the practice and interstate distribution of compounded drugs. Many of the people involved in drafting the original legislation and familiar with the Modernization Act feel that the MOU does not accurately represent the original intent of Congress. The MOU places further unnecessary restrictions on consumer choices and commonly accepted professional pharmacy compounding practices. State agencies, pharmacists, doctors, and healthcare consumers have expressed enough concern that the FDA has extended the comment period until June 1, 1999. But there is no guarantee that the MOU will be revised to adequately address those concerns. *Now is the time to make your voice heard!*

**THE FUTURE (IF THE MOU IS APPROVED):** *Many consumers and doctors would no longer have access to some compounded drugs that are currently used as effective treatments.* Compounded drugs are often alternative solutions for individuals who have difficulty with or toxic reactions to patented (noncompounded) drugs. Others simply need or prefer the more specialized treatment or natural ingredients that compounded drugs offer. With the MOU, the FDA would restrict these options if the drug is not compounded in your state. Furthermore, if you travel across state lines, you may not be able to order the drug and have it shipped to you.

The MOU will *limit the rights of pharmacists to suggest alternatives to physicians and patients.* Pharmacists frequently inform patients and physicians of alternative drugs that may be better suited to treating a particular problem or symptom. This time-honored patient-physician-pharmacist relationship is jeopardized because the MOU labels this common professional practice solicitation, if the alternative is a compounded drug. In effect, the MOU places a gag order on pharmacists who specialize in compounded drugs.

By severely limiting the interstate distribution of compounded prescriptions, with no concern for limiting the same distribution practices for noncompounded prescriptions, the MOU *threatens the economic survival of specialty pharmacies, further restricting consumer choices.* Specialty pharmacies currently fill a unique niche in response to the increasing demand for custom-compounded drugs, such as those using natural ingredients as an alternative to patented synthetics. Equal treatment under the law is called for.

**WHAT WE CAN DO TO ENSURE A BETTER FUTURE:** We must all take responsibility for making the FDA hear our concerns. *Each of us must provide **WRITTEN** comment to the FDA requesting that the MOU be amended no later than May 27, 1999* (so they can be received by the June 1 deadline). Please note that your comments must be in writing to be considered valid by the FDA. Sending the attached postcard is the easiest way to register your comments. However, writing a letter is the most effective way to make sure the FDA is aware of specific issues regarding the MOU. If you need help, specific wording is suggested in a draft letter available at [www.wipws.com/letter.htm](http://www.wipws.com/letter.htm) on our website.

Submit written comments (*including the docket number reference*) to:

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857-0003

RE: Docket No. 98N-1265

***IT IS VITAL that you also contact your U.S. Congress officials in both the House and the Senate to register your disapproval of the MOU as currently drafted.*** E-mail and postal addresses are available on the Internet at:

[www.house.gov/house/MemberWWW.html](http://www.house.gov/house/MemberWWW.html)  
and  
[www.senate.gov](http://www.senate.gov)

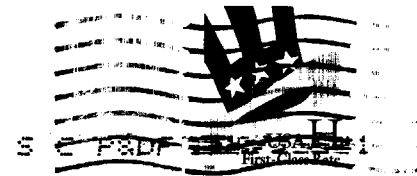
for the House and Senate, respectively. *Make sure to mention the docket number and that you want the MOU amended.* You can state that, "in its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice, and infringes on the rights of compounding pharmacists to serve the public's medical needs."

For more information about the MOU, or a copy of the official MOU draft, please see [www.fda.gov/cder/pharmcomp](http://www.fda.gov/cder/pharmcomp) on the Internet.

***We at Women's International Pharmacy thank you  
for your support in this urgent matter.  
We look forward to continuing to provide you with superior  
custom-compounded products and related services.***

**SUNRISE, Ltd.**

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